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10/527,263

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EXAMINER

HOWARD, ZACHARY C

ART UNIT

PAPER NUMBER

1646

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,263	<b>Applicant(s)</b> SMALL ET AL.	
	<b>Examiner</b> ZACHARY C. HOWARD	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6,11-13 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,11-13 and 18 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/19/08</u> .                                                 | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 6/16/08 has been entered in full. Claims 1, 2, 6, 11, 12, 13 and 18 are amended. Claims 4 and 5 are canceled (claims 7-10, 14-17 and 19-23 were previously canceled).

In the 10/30/07 Office Action, Applicants were required to elect a single species of cardiovascular disease. Applicants' election of the species of heart failure in the reply filed on 11/28/07 was acknowledged in the Office Action mailed 2/6/08. In the 6/16/08 claim amendments, independent claim 1 has been limited to the species of heart failure. Therefore, the species election is hereby *withdrawn*; however, it will be reinstated if claims with broader scope than the species of heart failure are subsequently submitted.

Claims 1-3, 6, 11, 12, 13 and 18 are pending and under consideration.

### ***Information Disclosure Statement***

The Information Disclosure Statement of 5/19/08 has been considered.

### ***Withdrawn Objections and/or Rejections***

The following page numbers refer to the previous Office Action (2/6/08).

The objection to the specification at pg 2 is *withdrawn* in view of Applicants' amendments to the specification. However, see the new objection to the specification set forth below.

All rejections of claims 4 and 5 are moot in view of Applicants' cancellation of these claims.

The objections to claims 1, 2 and 12 at pg 2-3 are *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claims 1-3, 6, 11-13 and 18 under 35 U.S.C. § 112, first paragraph at pg 4-9 for failing to provide enablement for the full scope of the claims is *withdrawn* in view of Applicants' amendments to the claims.

Art Unit: 1646

The rejection of claims 1-3, 6, 11-13 and 18 under 35 U.S.C § 112, second paragraph at pg 9 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is *withdrawn* in view of Applicants' amendments to claims 1 and 11.

### ***Maintained Objections and/or Rejections***

#### ***Claim Objections***

Claim 13 is objected to because of the following informalities:

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This objection was set forth previously at pg 2-3 of the 2/6/08 Office Action.

Applicants' arguments (6/16/08; pg 5) as they pertain to the objection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response, Applicants have amended claim 13 and argue that the objected claims "have been amended to correct these inadvertant and/or typographical errors".

Applicants' arguments have been fully considered but are not found persuasive. Applicants have amended claim 13 and parent claim 6 to narrow "cardiovascular disease" to "heart failure". The wording of claim 13 has been changed but still does not further limit parent claim 6. As amended claim 6 recites, "the therapy regimen delays development of heart failure in the individual". As amended claim 13 recites, "wherein the therapy regimen delays development of heart failure by delaying progression or early death associated with the heart failure". Delaying progression associated with heart failure encompasses the same scope as delaying development of heart failure. Furthermore, delaying early death associated with heart failure is inherent to delaying development of heart failure (i.e., heart failure leads to earlier death; therefore delaying such failure delays early death). As such, claim 13 fails to further limit the subject matter of parent claim 6.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6, 11-13 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection was set forth previously at page 3-4 of the 2/6/08 Office Action.

Applicants' arguments (6/16/08; pg 5-6) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response, Applicants argue that independent claim 1 has been amended "to recite a step of "outputting result of risk assessment for the individual"" and "thus recites a useful, concrete, and tangible result, the outputted result of the risk assessment for the individual".

Applicants' arguments have been fully considered but are not found persuasive. It is maintained that claims 1-6, 11-13 and 18 each encompass a method that is a judicial exception to 35 U.S.C. 101 (i.e., an abstract idea) and is not directed to a practical application of such judicial exception (e.g., because the claim does not require any physical transformation and the invention does not produce a useful, concrete and tangible result). Each of steps (a)-(c) recited in the method of claim 1 is a mental step (i.e., no physical transformations are required by the method steps). "Obtaining information regarding the presence or absence of a deletion" in a protein (as recited in steps (a) and (b) of claim 1) does not require that the deletion is physically measured as part of the method. Furthermore, assessing risk (as in step (c) of claim 1) is solely a mental determination. Furthermore, "selecting a therapy" (as recited in each of dependent claims 6, 11, 12, 13 and 18) is also solely a mental determination.

Applicants have amended claim 1 to recite "d. outputting result of the risk assessment for the individual". The term "outputting" is not defined in the specification and broadly encompasses computer-printed output, hand-written output, spoken output, typed output (i.e., typing the result on a keyboard), display on a computer screen,

Art Unit: 1646

saving the result on a computer disk, and more. Since it is not specified what the assessment is being outputted from, "outputting" also broadly encompasses moving the assessment from one portion of a computer to another (i.e., copying the assessment from one folder in a computer to another). In all such cases, "outputting" is merely moving the assessment from one physical storage location to another without providing a transformation or reduction of an article to a different state or thing. Even a sheet printed with the assessment has not been transformed: the sheet is still a sheet with no structural relationship to the information that is printed upon it. In all such cases, the "output" is not a tangible result because it is still just an abstract mental concept without a real-world result; the abstract mental concept has just been moved from the brain or a computer to a different storage device.

It is noted that claim 1 originally recited "detecting the presence or absence" of a deletion in a protein in each of steps (a) and (b). If the claims were amended, for example, to use this claim language, the claims would be directed to statutory subject matter, because the claimed method would require a physical detection step.

***New objections and/or rejections necessitated by Applicants' amendment  
Specification***

The amendment filed 6/16/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. In the amendment to the specification filed on 6/16/08, the specification was amended to add a new first paragraph with a priority claim to PCT/US03/028135 and 60/409167. The amended paragraph also states that "both of which are incorporated by reference in their entirety". This statement is new matter, because the originally filed specification did not indicate that the priority documents were incorporated in their entirety. In particular, a provisional application such as 60/409167 may have additional subject matter that is not present in a later filed application. Therefore, any incorporation of reference of the subject matter

Art Unit: 1646

of the provisional application must be present at the time of filing of an application, and the later addition of such a statement is new matter.

Applicants are required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112, 1st paragraph, new matter***

Claims 1-3, 6, 11-13 and 18 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter.

Independent claim 1 was amended on 6/16/08 to add the method step of "d. outputting result of the risk assessment for the individual". This recitation is new matter for the following reasons. The specification as originally filed does not teach a method step of "outputting result of the risk assessment for the individual". The specification does not define the term "outputting". As such, the method step broadly encompasses computer-printed output, hand-written output, spoken output, typed output (i.e., typing the result on a keyboard), display on a computer screen, saving the result on a computer disk, moving the assessment from one portion of a computer to another (i.e., copying the assessment from one folder in a computer to another), and more. The specification as originally filed does not provide support for a method comprising an outputting step that constitutes any of these forms of output, either individually or generically. At page 5-6 of the response, Applicants argue support for the limitation exists in various places in the specification. The Examiner has fully considered each of the teachings pointed to by Applicants but does not find persuasive that any provides support for the recited method step. Applicants point to pages 15 and 16 of the specification as teaching "providing results in the form of a prognosis, diagnosis, direction of life-style changes" (pg 15) and "providing results as a therapy regimen" (pg 16). However, the paragraph bridging pages 15-16 (which appears to be the teaching referred to by Applicants) merely provides a definition of "assessment" as "referring to the prognosis, diagnosis, monitoring, delaying development, delaying progression, delaying early death, risk for developing, staging, predicting progression, predicting response to therapy regimen, tailoring response to a therapy regiment, predicting or

Art Unit: 1646

directing life-style changes that alter risk or clinical characteristics..." This teaching is solely directed to defining the "assessment" and as such informs step (c) of the claim but does not provide any teaching regarding "outputting" such an assessment.

Applicants point to page 17 as teaching "outputting results as a specific pharmacologic therapy with  $\alpha_2$ AR agonists or antagonists and/or  $\beta$ AR agonists or antagonists".

However, page 17 merely provides a definition of "therapy regimen" as referring to "a procedure for delaying development, delaying progression, or delaying early death associate with a cardiovascular disease". This teaching is solely directed to defining a "therapy regimen" and as such informs the additional step of dependent claim 6 but does not provide any teaching regarding "outputting" an assessment as recited in part (d) of claim 1. Applicants point to page 18 as teaching "suggesting prophylactic therapy in response to the assessment". However, page 18 merely teaches that some individuals at risk for developing heart failure may also benefit from prophylactic therapy, and does not provide any teaching regarding "outputting" an assessment as recited in part (d) of claim 1. Applicants point to page 20-21 as teaching "describing statistical analyses conducted to test for interactions between the  $\alpha_{2C}$ AR and  $\beta_1$ AR polymorphisms". However, this teaching is merely a description of a statistical analysis that can be performed as part of an "assessment" and does not provide any teaching regarding "outputting" an assessment as recited in part (d) of claim 1. Applicants point to page 19-20 as teaching "describing genotyping methods for determining the presence/absence of polymorphisms as a part of the result associated with the methods". However, this teaching is merely a description of a method of determining the presence or absence of a polymorphism (i.e., a measurement step such as steps (a) and (b)), and does not provide any teaching regarding "outputting" an assessment as recited in part (d) of claim 1. In summary, new step (d) of claim 1 is new matter.

Claims 2, 3, 6, 11, 12, 13 and 18 are including in this rejection because they depend from claim 1 and include the same new matter.

### ***Conclusion***

No claims are allowed.



Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./

Examiner, Art Unit 1646

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646

Application/Control Number: 10/527,263  
Art Unit: 1646

Page 9